

REMARKS

Claims 14, 17 and 19-25 are pending and stand rejected in the Office Action. Applicants have cancelled claims 14, 17, and 20-25. In addition, Applicants have amended claim 19 and added new claims 26-28. Upon entry of the amendments, claims 19 and 26-28 remain pending.

Support for the amendments is found in the specification as originally filed. Claim 19 has been amended to address a formal matter and to recite that the diet contains the listed ingredients on a dry weight basis. Support for the amendment is found on page 2, line 2 of the specification. Support for new claim 26 is found for example on pages 2 and 3 of the specification. Support for new claim 27 is found for example on page 2, lines 26-31. Support for new claim 28 is found for example on page 3, lines 13-26 and in the Table on page 6 of the specification. Applicants respectfully request entry of the amendments.

REJECTIONS UNDER 35 U.S.C. § 112

Claims 14, 17 and 20-25 are rejected under 35 U.S.C. § 112, first and second paragraphs, as failing to comply with the written description requirement, and as being indefinite. Applicants have cancelled the claims, mooted the rejection. Applicants respectfully request the rejection be withdrawn.

Claim 19 is rejected as indefinite. Applicants have amended claim 19 in accord with the recommendation of the Examiner and respectfully request the rejection be withdrawn.

Claims 20-23 are considered indefinite. Applicants have cancelled claims 20-23, mooted the rejection.

REJECTIONS UNDER 35 U.S.C. § 103

Claims 14, 17, and 19-25 are rejected under 35 U.S.C. § 103 as obvious over the Shields reference (U.S. Patent No. 6,156,355) in view of the Wadsworth reference (U.S. Patent No. 6,737,089) and the Klimberg article (Arch Surg. 1990), and further in view of

Taber's Cyclopedic Medical Dictionary (1997). Applicants have cancelled claims 14, 17, and 20-25. As to amended claim 19 and the new claims, Applicants respectfully traverse the rejection and request reconsideration.

A novel invention is patentable unless the invention as a whole would have been obvious to a person of ordinary skill in the art. The invention as a whole inquiry includes consideration of advantages arising from the invention whether they are claimed or not. In assessing obviousness, there must first be considered the differences between the invention and the combined references. Then the level of skill in the art is determined, and an assessment of obviousness is made. It follows that the relative sophistication of a person of skill in the art must be considered when assessing the particular teachings of a reference or a combination of references. That is, the references are considered for what they teach to a person of ordinary skill. The rejections over the cited art are discussed below with these principles in mind.

The Shields reference does not contain any teaching that would motivate a person of skill in the art to combine the four components recited in the claims in a diet for eliminating diarrhea in cats with inflammatory bowel disease (IBD). The whole reference is geared only toward dogs, and indeed to compositions specific to particular breeds of dogs. And in fact, the Shields reference contains general teachings with little specific information. It broadly discloses dog foods that contain a wide variety of conventional foods, such as chicken and rice and the like, and in addition a long list of herbs, vitamins, and other nutraceuticals. The general nature of the teachings of the reference is reflected in its claims and examples, which recite food compositions with dozens of components. The compositions are alleged to maintain health of the dogs fed the diet. Applicants submit that cat and dog diets differ enough that general teachings about dog foods, as in Shields, would not make methods obvious of treating specific symptoms from a specific disease in cats.

The Office Action accurately states that all four components of the claimed diet are mentioned in the reference, but that no levels are given. Applicants respectfully submit that the deficiency of the reference goes even farther, in that even the reference's

disclosure of the four components would not motivate the person of skill to select those components for a diet to treat cats suffering from IBD. There is little formulation guidance in the reference, and no clinical data presented to motivate the skilled person to give weight to its teaching. When the Shields reference is considered in its entirety by the person of skill in the art, there is no reason to suspect that a diet containing the four claimed components would be likely to have the beneficial effect in cats when fed to patients having diarrhea resulting from IBD. The reference actually provides no real motivation to provide diets containing all four of the claimed components.

Against these deficiencies of the Shields reference, Applicants respectfully submit that the secondary references do not amount to a motivation to combine their teachings with Shields to provide the claimed invention. Applicants submit that even if the Wadsworth reference taught glutamine, 5-10% by weight, as an additive to animal diets¹, and even assuming the Klimberg reference teaches feeding a diet with 3% glutamine to rats (not cats) suffering gastrointestinal distress, the person of skill in the art would have no motivation or apparent reason to combine these references to arrive at the claimed method for eliminating runny, soft and unformed stools in cats that have diarrhea resulting from IBD.

Applicants are not arguing against the combined references separately, nor are they attacking the *prima facie* case by attacking the references individually. They do wish, however, to point out the nature of the primary reference, in order to show that there is no motivation or apparent reason to combine the primary Shields reference with any of the secondary references, outside of the teachings of the current specification.

For the above reasons, the Applicants respectfully request that the obviousness rejection of claim 19 be withdrawn.

¹ It doesn't. Applicants note that the Wadsworth reference does not disclose feeding a diet containing 5% to 10% by weight of glutamine, but rather feeding a water solution with those levels of glutamine as a supplement to an animal's diet.

New claims 26-28 further limit patentable claim 19. On this basis, Applicants submit that claims 26-28 are also non-obvious in light of the references. Accordingly, Applicants respectfully request they be passed to a state of allowability.

Claims 14, 17, and 19-25 are rejected under 35 U.S.C. § 103 as obvious over the Chandler reference (*In Practice*, 2002). Applicants respectfully traverse the rejection as applied to the amended claims and request reconsideration.

Applicants respectfully submit that even the more authoritative (in comparison to Shields, *supra*) Chandler reference does not rise to motivation to do what the Applicants have done. As understood by a person of skill in the art, the Chandler reference provides a broad overview of the management of gastrointestinal disease in dogs and cats. As expected, such a broad overview includes a wide variety of observations and guidelines for the diet of dogs and cats with gastrointestinal disease. Thus, the Chandler reference makes recommendations as to cottage cheese, rice, glutamine, carbohydrates, lactose, resistant starches, fiber, fats, medium chain triglycerides, omega-3 fatty acids, vitamins and minerals, and so on. It recommends a highly digestible diet that contains a novel protein source, is gluten free and has moderate fat restriction, and is fed as frequent small meals. It states,

“Other dietary modifications may include an increase in fermentable soluble and, possibly, insoluble fiber in colonic disease. Increases in dietary omega-3 fatty acids, FOS, antioxidants, and probiotics may also be beneficial in some cases.”

Against the broad non-specific teachings of the Chandler reference drawn to gastrointestinal disease generally, Applicants have invented and are claiming a method specifically for treating diarrhea in a cat suffering in particular from IBD. According to the claims, the diet to be fed such a cat contains defined limits of four components on a dry weight basis: glutamine, fermentable fibers, antioxidants, and omega-3 fatty acids. Applicants offer experimental observations that a diet containing all four components completely eliminates watery stools and soft unformed stools (i.e., the “class 1” and “class 2” stools of the stool monitoring scoring given in Example 1). At the same time, Applicants demonstrate that diets containing some but not all of the recited

components are not as effective against diarrhea in cats with IBD. Examples include Food A, with 42%, Food B with 15%, and Food D with 7% class 1 or class 2 stools. Applicants submit such a result is not derivable from the teachings of the Chandler reference, and that the invention as a whole would not have been obvious in view of Chandler.

Claim 26 restricts the four components to narrower weight ratios than the broader claim 19. Claim 27 specifically claims the use of vitamin C and vitamin E as antioxidants. Claim 28 recites the discovered advantage that feeding a cat a diet containing specifically the four claimed components totally eliminates the production of Type 1 and Type 2 stools (i.e., watery, runny, or soft and unformed). Applicants submit that the dependent claims 26-28 are patentable over Chandler for these further reasons.

Seen in this light, the Chandler reference seems merely to give conclusory guidelines and an invitation to experiment. Neither the reference, nor the knowledge of the person of skill in the art provides any motivation or apparent reason to modify Chandler to arrive at the subject matter of the amended claims, nor any reason to expect the recited diet would provide the noted advantages. For this reason, Applicants respectfully request that the rejection be withdrawn.

CONCLUSION

For the reasons discussed above, Applicants believe that claims 19 and 26-28 are in an allowable condition and respectfully request an early Notice of Allowance. The Examiner is invited to telephone the undersigned if that would be helpful to resolving any issues.

Respectfully submitted,

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